"Tobacco Product Establishment Registration and Submission of Certain Health Information"
(OMB Control Number 0910-0650)

Change Request (83-C)

September 15, 2017

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to include a revised version of the associated Registration and Listing guidance. OMB has concurred with the submission of this change request.

We are seeking OMB's approval for the use of a change request to account for decreased PRA estimates due to the minor guidance revisions.

We seek to revise the guidance to provide registrants a compliance policy which states that, in lieu of multiple label submissions, a single labeling submission (i.e. "package label plan") may be submitted in certain circumstances. This limited revision seeks to reduce the burden and time on registrants and increase the efficiency for labeling submissions. There are no substantive changes being made in the revised guidance.

Based on the new compliance policy, FDA estimates a decrease of 2,591 hours for the registration and product listing and ingredient listing collection. We have re-estimated Table 1.--Estimated Annual Reporting Burden on page 12 (below).


0910-0650
supporting statement

Additionally, FDA has also updated the burden charts to remove information from a previous revision that is no longer necessary.